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| EXAMINER |
|---|
| HO, ALLEN C |

| ART UNIT | PAPER NUMBER |
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| 2882 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 10/033,327 | Applicant(s) GRAF, ULRICH MARTIN | |
|---|---|---|---|
| | Examiner Allen C. Ho | Art Unit 2882 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22-25* is/are allowed.

6)☒ Claim(s) *1, 3-10, 12-21 and 26* is/are rejected.

7)☒ Claim(s) *2 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 209 (page 9, paragraph 30, line 7). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 316 (Fig. 3D). A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the internal seed acting as a marker for the target volume must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a diagnostic energy source attached to a translatable end of a second gantry must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

5. The disclosure is objected to because of the following informalities:

(1) Page 8, paragraph 28, line 9, "220" should be replaced by --208--.

(2) Page 9, paragraph 30, line 8, "227" should be replaced by --220--.

Appropriate correction is required.

### *Claim Objections*

6. Claim 1 is ambiguous as it fails to set forth the required interrelationship between the first and the second gantries (MPEP 2172.01).

### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 14, 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticiapted by Brown *et al.* (U. S. Patent No. 5,751,781).

With regard to claim 14, Brown *et al.* disclosed a method (Figs. 10-12) for applying radiation, comprising: positioning a diagnostic radiation source (SO) to be in alignment with a target volume (**2**); positioning an imager (**100**) to receive radiation from the diagnostic radiation source; positioning a therapeutic radiation source (**4**) to be in alignment with the target volume; and re-positioning the imager to receive radiation from the therapeutic radiation source (Fig. 12).

With regard to claim 15, Brown *et al.* disclosed the method of claim 14, further comprising: propagating the diagnostic radiation (IB) toward the target volume; receiving the diagnostic radiation by the imager after passing through the target volume (Fig. 10); positioning the therapeutic radiation source is based on results of the diagnostic radiation to the imager (column 15, lines 3-5); propagating the therapeutic radiation into the target volume (Fig. 12); receiving the therapeutic radiation by the imager after passing through the target volume (Fig. 12); and generating verification data by the imager from the therapeutic radiation (column 15, lines 23-24).

With regard to claim 16, Brown *et al.* disclosed the method of claim 14, wherein the imager is a multiple-energy imaging unit (detecting radiations from a KeV diagnostic radiation source and an MeV therapeutic radiation source).

With regard to claim 19, Brown *et al.* disclosed the method of claim 15, further comprising generating a cone x-ray beam where volumetric information can be constructed (column 16, lines 39-45).

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3-10, 12, 13, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanover (U. S. Patent No. 6,104,780) in view of Watanabe (U. S. Patent No. 6,325,537 B1).

With regard to claim 1, Hanover *et al.* disclosed an apparatus (Fig. 2) comprising: a first radiation source (**140**) attached to a first gantry (**116**); at least one second radiation source (**142**); a second gantry (**118**) that is rotatable; and an imager (**146**).

However, Hanover *et al.* did not teach that the imager is attached to an articulable end of the second gantry.

Watanabe disclosed a C-shaped gantry (**14**) that comprises an imager (**16**) attached to an articulable end (**20**) of the gantry and a rotatable x-ray source (**12**). This arrangement makes the apparatus applicable to a wide range of clinical applications (column 4, lines 29-51).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the C-shaped gantry disclosed by Hanover *et al.* to include an imager attached to an articulable end of the gantry and a rotatable x-ray source according to Watanabe, since a person would be motivated to use the same apparatus for as many different clinical applications as possible, which is less expensive than purchasing additional application-specific equipments.

With regard to claim 3, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein at least one second radiation source is attached to the second gantry.

With regard to claim 4, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein the first radiation source is capable of propagating therapeutic energy (x-rays could be used as therapeutic radiations).

With regard to claim 5, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein at least one second radiation source is capable of propagating diagnostic energy (x-ray).

With regard to claim 6, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein the first gantry is rotatable.

With regard to claim 7, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 6, wherein the first gantry and the second gantry are rotatable about a common pivot axis (Hanover *et al.* **132**).

With regard to claim 8, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein the imager is a multiple-energy imaging unit (all x-ray imagers are sensitive to a range of energies).

With regard to claim 9, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein the articulable end includes at least one pivot point between the second gantry and the imager (Watanabe Fig. 2).

With regard to claim 10, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein the articulable end includes a sliding mechanism (Watanabe Fig. 9) capable of translating the imager in a plane.

With regard to claim 12, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 1, wherein the articulable end (Watanabe **20**) is capable of folding the imager against the second gantry.

With regard to claim 13, Hanover *et al.* as modified Watanabe disclosed the apparatus of claim 7, wherein the second gantry is nestled within the first gantry (Hanover *et al.* Fig. 2).

With regard to claim 26, Hanover *et al.* as modified Watanabe disclosed all the elements except that the diagnostic energy source is attached to a translatable end of the second gantry.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide translational degrees of freedom to the diagnostic energy source, since a person would be motivated to maintain consistent image brightness by keeping the diagnostic energy source normal to the imaging unit. As disclosed by Watanabe, the entire body could be imaged by translating the imaging unit while rotating the source (Figs. 10 and 12). In doing so, however, the incident angle changes at different locations, thereby causing the source intensity to vary at different locations. A person skilled in the art would recognize this and provide a translation mechanism to the source so that the source could move in a plane parallel with the imaging unit in order to maintain the normal incident angle.

11. Claim 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Brown *et al.* (U. S. Patent No. 5,751,781) as applied to claim 14 above, and further in view of Kunieda *et al.* (U. S. Patent No. 6,307,914 B1).

With regard to claim 17, Brown *et al.* disclosed the method of claim 14. However, Brown *et al.* did not teach placing an internal seed to act as a marker for the target volume.

Kunieda *et al.* disclosed an internal marker (**17**) for locating the position of a tumor for radiation treatment.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to place an internal marker for the target volume, since a person would be motivated to accurately locate and track the target volume for irradiation.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown *et al.* (U. S. Patent No. 5,751,781) as applied to claim 15 above.

With regard to claim 18, Brown *et al.* disclosed the method of claim 15. However, Brown *et al.* did not teach that the method further comprising generating multiple diagnostic radiation slices using a fan x-ray beam to provide a 3-dimensional reconstruction of the target volume.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to generate multiple diagnostic radiation slices using a fan x-ray beam to provide a 3-dimensional reconstruction of the target volume. While Brown *et al.* did not specifically teach using a fan beam for three-dimensional reconstruction of the target volume, a person skilled in the art would recognize that a fan beam is just a thin cone beam, which could be produced by narrowing the collimators in the slice direction. There might be times when the narrower dimension of a fan beam is more appropriate for specific situations or target volumes, and a person skilled in the art would be motivated to use a fan beam according to the circumstances.

13. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown *et al.* (U. S. Patent No. 5,751,781) as applied to claim 15 above, and further in view of Kunieda *et al.* (U. S. Patent No. 6,307,914 B1).

With regard to claims 20 and 21, Brown *et al.* disclosed the method of claim 15. However, Brown *et al.* did not teach that the diagnostic radiation could be operated continuously or in a pulsed manner to provide a fluoroscopic image of moving internal anatomy.

Kunieda *et al.* disclosed a method for applying radiation, comprising operating the diagnostic radiation to provide a fluoroscopic image of moving internal anatomy.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to operate the diagnostic radiation to provide a fluoroscopic image of moving internal anatomy, since a person would be motivated to track the motion of a moving internal anatomy in order to direct the therapeutic radiation at the correct position.

Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to operate the diagnostic radiation continuously or in a pulsed manner, since a person would to motivated to refresh the image at rate that is comparable to the rate of change in the position of the moving internal anatomy in order to keep the x-ray dosage at a minimum. For instance, one might wish to update the image at a rate that is comparable to the heart rate when one is imaging the heart.

***Allowable Subject Matter***

14. Claims 2 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter:

With regard to claim 2, although the prior art discloses an apparatus of claim 1, it fails to teach or fairly suggest at least one second radiation source is attached to the first gantry.

With regard to claim 11, although the prior art discloses an apparatus of claim 1, it fails to teach or fairly suggest one of at least one second radiation source is attached to a sliding mechanism capable of extending and retracting the second radiation source from the second gantry.

16. Claims 22-25 are allowed.

17. The following is an examiner's statement of reasons for allowance:

With regard to claims 22-25, although the prior art discloses a method for imaging radiation comprising:

positioning a multiple-energy imaging unit normal to a first axis to receive radiation at a first energy level,

propagating radiation by a first radiation source at the first energy level along the first axis,

position a second radiation source along the first axis,

maintaining the multiple-energy imaging unit normal to the first axis to receive radiation by the second radiation source, and

propagating radiation by the second radiation source,

it fails to teach or fairly suggest retracting the first radiation source.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

(1) Oota (U. S. Patent No. 6,508,586 B2) disclosed an IVR-CT apparatus comprising two gantries and two radiation sources.

(2) Danielsson *et al.* (U. S. Patent No. 6,429,578 B1) disclosed a multiple-energy imager.

(3) Ivan *et al.* (U. S. Patent No. 6,031,888) disclosed a fluoro-assist feature for a diagnostic imaging device.

(4) Shepherd *et al.* (U. S. Patent No. 5,537,452) disclosed a radiation therapy system comprising a CT apparatus.

(5) Swerdloff *et al.* (U. S. Patent No. 5,392,452) disclosed a radiation therapy system comprising a diagnostic apparatus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allen C. Ho whose telephone number is (703) 308-6189. The examiner can normally be reached on Monday - Friday from 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached at (703) 308-4858. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0530.

Allen C. Ho
Examiner
Art Unit 2882

ACH
June 25, 2003

EDWARD J. GLICK
Supervisory Patent EXAMINER
TECHNOLOGY CENTER 2800